

or after December 6, 1998, immediately upon initial startup of the source.

(3) All sterilization chamber vents at sources using less than 1 ton of ethylene oxide that increase their ethylene oxide usage after December 6, 1998 such that the sterilization chamber vent becomes subject to the emissions standards in §63.362(c), immediately upon becoming subject to the emission standards.

(4) All aeration room vents subject to the emissions standards in §63.362 with an initial startup date before December 6, 2000, no later than December 6, 2000.

(5) All aeration room vents subject to the emissions standards in §63.362 with an initial startup date on or after December 6, 2000, immediately upon initial startup of the source.

(6) All aeration room vents at sources using less than 10 tons that increase their ethylene oxide usage after December 6, 2000, such that the aeration room vents become subject to the emissions standards in §63.362, immediately upon becoming subject to the emission standards.

(7)-(10) [Reserved]

[59 FR 62589, Dec. 6, 1994, as amended at 61 FR 27788, June 3, 1996; 63 FR 66994, Dec. 4, 1998; 64 FR 67793, Dec. 3, 1999; 64 FR 69643, Dec. 14, 1999; 66 FR 55582, Nov. 2, 2001; 70 FR 75345, Dec. 19, 2005]

#### § 63.361 Definitions.

Terms and nomenclature used in this subpart are defined in the Clean Air Act (the Act) as amended in 1990, §§63.2 and 63.3 of subpart A of this part, or in this section. For the purposes of subpart O, if the same term is defined in subpart A and in this section, it shall have the meaning given in this section.

*Aeration room* means any vessel or room that is used to facilitate off-gassing of ethylene oxide at a sterilization facility.

*Aeration room vent* means the point(s) through which the evacuation of ethylene oxide-laden air from an aeration room occurs.

*Baseline temperature* means a minimum temperature at the outlet from the catalyst bed of a catalytic oxidation control device or at the exhaust point from the combustion chamber of a thermal oxidation control device.

*Chamber exhaust vent* means the point(s) through which ethylene oxide-laden air is removed from the sterilization chamber during chamber unloading following the completion of sterilization and associated air washes.

*Compliance date* means the date by which a source subject to the emissions standards in §63.362 is required to be in compliance with the standard.

*Deviation* means any instance in which an affected source, subject to this subpart, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart including, but not limited to, any emission limitation (including any operating limit) or work practice standard;

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the operating permit for any affected source required to obtain such a permit; or

(3) Fails to meet any emission limitation (including any operating limit) or work practice standard in this subpart during startup, shutdown, or malfunction, regardless of whether or not such failure is permitted by this subpart.

*Effective date* means the date of promulgation in the FEDERAL REGISTER notice.

*Initial startup date* means the date when a source subject to the emissions standards in §63.362 first begins operation of a sterilization process.

*Manifolding emissions* means combining ethylene oxide emissions from two or more different vent types for the purpose of controlling these emissions with a single control device.

*Maximum ethylene glycol concentration* means any concentration of ethylene glycol in the scrubber liquor of an acid-water scrubber control device established during a performance test when the scrubber achieves at least 99-percent control of ethylene oxide emissions.

*Maximum liquor tank level* means any level of scrubber liquor in the acid-water scrubber liquor recirculation tank established during a performance test when the scrubber achieves at least 99-percent control of ethylene oxide emissions.

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*Oxidation temperature* means the temperature at the outlet point of a catalytic oxidation unit control device or at the exhaust point from the combustion chamber for a thermal oxidation unit control device.

*Source(s) using less than 1 ton* means source(s) using less than 907 kg (1 ton) of ethylene oxide within all consecutive 12-month periods after December 6, 1996.

*Source(s) using 1 ton* means source(s) using 907 kg (1 ton) or more of ethylene oxide within any consecutive 12-month period after December 6, 1996.

*Source(s) using 1 to 10 tons* means source(s) using 907 kg (1 ton) or more of ethylene oxide in any consecutive 12-month period but less than 9,070 kg (10 tons) of ethylene oxide in all consecutive 12-month periods after December 6, 1996.

*Source(s) using less than 10 tons* means source(s) using less than 9,070 kg (10 tons) of ethylene oxide in all consecutive 12-month periods after December 6, 1996.

*Source(s) using 10 tons* means source(s) using 9,070 kg (10 tons) or more of ethylene oxide in any consecutive 12-month period after December 6, 1996.

*Sterilization chamber* means any enclosed vessel or room that is filled with ethylene oxide gas, or an ethylene oxide/inert gas mixture, for the purpose

of sterilizing and/or fumigating at a sterilization facility.

*Sterilization chamber vent* means the point (prior to the vacuum pump) through which the evacuation of ethylene oxide from the sterilization chamber occurs following sterilization or fumigation, including any subsequent air washes.

*Sterilization facility* means any stationary source where ethylene oxide is used in the sterilization or fumigation of materials.

*Sterilization operation* means any time when ethylene oxide is removed from the sterilization chamber through the sterilization chamber vent or the chamber exhaust vent or when ethylene oxide is removed from the aeration room through the aeration room vent.

*Thermal oxidizer* means all combustion devices except flares.

[59 FR 62589, Dec. 6, 1994, as amended at 66 FR 55583, Nov. 2, 2001]

§ 63.362 Standards.

(a) Each owner or operator of a source subject to the provisions of this subpart shall comply with these requirements on and after the compliance date specified in § 63.360(g). The standards of this section are summarized in Table 1 of this section.

TABLE 1 OF SECTION 63.362—STANDARDS FOR ETHYLENE OXIDE COMMERCIAL STERILIZERS AND FUMIGATORS

Existing and new sources	Source type	Sterilization chamber vent	Aeration room vent	Chamber exhaust vent
Source size .....	<907 kg (<1 ton) .....	No control required; minimal recordkeeping requirements apply (see § 63.367(c)).		
	≥907 kg and <9,070 kg (≥1 ton and < 10 tons).	99% emission reduction (see § 63.362(c)).	No control .....	No control.
	≥9,070 kg (≥10 tons) ....	99% emission reduction (see § 63.362(c)).	1 ppm maximum outlet concentration or 99% emission reduction (see § 63.362(d)).	No control.

(b) *Applicability of emission limits.* The emission limitations of paragraphs (c), (d), and (e) of this section apply during sterilization operation. The emission limitations do not apply during periods of malfunction.

(c) *Sterilization chamber vent at sources using 1 ton.* Each owner or operator of a sterilization source using 1 ton shall

reduce ethylene oxide emissions to the atmosphere by at least 99 percent from each sterilization chamber vent.

(d) *Aeration room vent at sources using 10 tons.* Each owner or operator of a sterilization source using 10 tons shall reduce ethylene oxide emissions to the atmosphere from each aeration room vent to a maximum concentration of 1